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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

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| BARBARA BERRY,<br><br>Plaintiff,<br><br>v.<br><br>MEDTRONIC, INC.; MEDTRONIC INTERNATIONAL TECHNOLOGY, INC.; and MEDTRONIC PUERTO RICO OPERATIONS CO.<br><br>Defendants. | Case No.: CV 08 2447 EMC<br><br>**COMPLAINT FOR DAMAGES, INJUNCTIVE AND DECLARATORY RELIEF**<br><br>**JURY TRIAL DEMANDED** |

Plaintiff, BARBARA BERRY, by her undersigned counsel, hereby commences this individual action against Medtronic, Inc., Medtronic International Technology, Inc., and Medtronic Puerto Rico Operations Co. (hereinafter collectively "Defendants" or "Medtronic," unless otherwise stated) for compensatory, equitable, injunctive, and declaratory relief. Plaintiff makes the following allegations based upon her personal knowledge as to her own acts, and upon information and belief, as well as upon her attorneys' investigative efforts as to Medtronic's actions and misconduct, and allege as follows:

## JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) because the parties are citizens of different States and the matter in controversy exceeds the jurisdictional amount exclusive of interest and costs.

2. Venue is proper under 28 U.S.C. §§ 1391 (a) and (c). Plaintiff resides in this District, and Defendants earn substantial compensation and profits from sales of Sprint Fidelis Leads in this District.

## INTRADISTRICT ASSIGNMENT

3. This action is appropriately assigned in the San Francisco Division because plaintiff Barbara Berry at all relevant times herein resided in Humboldt County and a substantial amount of the conduct giving rise to this action occurred in Humboldt County. Moreover, Plaintiff is informed and believes that defendant Medtronic is and was at all relevant times herein, authorized to do, and had regularly, continually and systematically done business in the State of California, including the City and County of San Francisco.

## PARTIES

4. Plaintiff, Barbara Berry, is and was at all relevant times a citizen of the City of Eureka, County of Humboldt, California.

5. Defendant, Medtronic, Inc. is a Minnesota Corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. Medtronic develops technology to treat conditions such as heart disease and other illnesses. Medtronic manufactures medical devices and sells them worldwide. Medtronic's Cardiac Rhythm Disease Management Division ("CRM Division") is the division that develops, researches, advertises, promotes, markets and sells all of Medtronic implantable defibrillators ("ICDs"), and Leads, some of which are marketed under the trade name "Sprint Fidelis." CRM Division's operations are principally conducted out of its facilities at Cardiac Rhythm Disease Management at 7000 Central Ave., Minneapolis, Minnesota 55432.

6. Defendant Medtronic International Technology, Inc. is a corporation existing by virtue of the laws of the territory of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

7. Defendant Medtronic Puerto Rico Operations Co., Inc, is a corporation existing by virtue of the laws of the territory of Puerto Rico, with its principal place of business at Road 149, km 56.3, Box 6001 Villalba, PR.

8. Medtronic International Technology, Inc. and Medtronic Puerto Rico Operations Co., Inc. are the wholly owned subsidiaries of Medtronic, Inc. and formulate, develop, manufacture and sterilize the devices at issue in this lawsuit.

## INTRODUCTION

9. Medtronic designs, researches, develops, manufactures, tests, markets, advertises, promotes, distributes, and sells products that treat cardiac arrhythmias, heart failure, and coronary and peripheral vascular disease. An arrhythmia is an irregular cardiac rhythm, which can cause significantly decreased cardiac output and ultimately, death. Medtronic holds itself out as "the global leader in medical technology, alleviating pain, restoring health and extending life for millions of people around the world." See 2005 Annual Statement, Medtronic, Inc.

10. A number of devices designed to detect and treat abnormally fast and irregular heart rhythms and to provide pacing for improper heart rhythms are available from Medtronic and other manufacturers, including implantable cardiac defibrillators ("ICDs"). ICDs contain pacemakers as well as defibrillators; while a pacemaker is used primarily to correct slow heart rates, an ICD detects and corrects both fast and slow heart rates. The pacemaker portion corrects the slow rates and the anti-tachycardia portion can "over-drive pace" rapid rates. The defibrillator portion can shock ventricular tachycardia and ventricular fibrillation to stop the heart and allow an appropriate rhythm to take over.

11. ICDs are designed to be implanted primarily under the skin of the chest wall. The device's power source, or pulse generator, is implanted in a pouch formed in the chest wall generally over the left pectoralis major muscle.

12. Typically, wires called Leads are inserted through a major vein and attached directly to the muscle on the inside of the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and can administer an electric shock to abort a dangerous "over-drive pace," a very rapid rhythm, or pace the heart at a normal rhythm if an irregularity is detected.

13. Such devices are used in patients, like the Plaintiff, who have arrhythmias or irregular heartbeats that are considered life-threatening. These arrhythmias or irregular heartbeats can result in the loss of consciousness or death, unless the patient receives therapy from an appropriate device to put the heart back into an appropriate cardiac rhythm.

14. If an implanted ICD and Lead operate properly, the system can save a patient's life. If either fails to operate, the patient may die within minutes.

## THE SPRINT FIDELIS LEADS

15. This Action seeks recovery for patients who has been implanted with Sprint Fidelis Leads marketed by Medtronic under the following model numbers:

(i) the 6949 LFJ extendable/retractable screw fixation (S) model

(ii) the 6948 LFH tuned fixation (T) model,

(iii) the 6931 LFT S fixation, and,

(iv) the 6930 LFK T fixation.

16. At all times relevant, these Sprint Fidelis Leads were researched, developed, manufactured, marketed, promoted, advertised, sold, and distributed by Medtronic to be used in connection with ICDs.

17. The majority of ICDs now use two or three Leads. As a result, smaller high-voltage Leads are attractive to electrophysiologists because they are believed to be easier to insert, and are less likely to obstruct blood flow or distort the tricuspid valve. The Medtronic Sprint Fidelis Leads are smaller high voltage Leads.

18. In 2001, Medtronic marketed its then-smallest defibrillation lead called the Sprint Quattro Secure, Model 6947 ("Quattro Leads").

19. In 2004, Medtronic introduced and marketed the Sprint Fidelis to replace the Sprint Quattro as the high voltage lead of choice and to attempt to gain a larger market share.

20. At the time that Medtronic announced the marketing of the Sprint Fidelis Leads, Medtronic claimed that "the small size of the Sprint Fidelis (Fidelis is a Latin word that means 'faithful') helps improve passage into a patient's venous system for an easier implant, and minimizes venous obstruction." Medtronic also referred to the Leads as "state-of-the-art."

21. Medtronic further represented that the Sprint Fidelis Leads were based on the "proven" design of the Quattro Leads.

22. The Sprint Fidelis Leads were approved for sale by the United States Food and Drug Administration (the "FDA") in September 2004 and have been implanted in over 160,000 patients worldwide.

23. The Sprint Fidelis Lead is a 6.6 French isodiametric multifilar true bipolar high voltage lead with silicone insulation and polyurethane outer coating. (One French is a measure of circumference in this instance. One French is equal to 0.33 mm, or approximately 0.012 inches.)

24. The Models 6949 and 6948 have two high voltage coils; the 6930 and 6931 models have a single right ventricular high voltage coil. As of January 2007, approximately 144,311 model 6949 Sprint Fidelis Leads, 7510 model 6948 Leads, 5387 model 6931 Leads, and 236 model 6930 Leads had been implanted.

## DEFECTS IN THE SPRINT FIDELIS LEADS

25. Since the Sprint Fidelis Leads were introduced to the market, it has become evident that a significant portion of the Leads have potentially fatal defects.

26. Such defects were discussed in an article written by doctors at The Minneapolis Heart Institute, one of the premiere heart institutes in the world, based on a study of the incidence of lead failures in the Sprint Fidelis Models compared to the Sprint Quattro Models. According to the report, which was prepared by Dr. Robert G. Hauser, et al., and published in the Heart Rhythm Society Journal in the Spring of 2007, "Early Failure of Small-Diameter High-Voltage Inflammable Cardioverter-Defibrillator Lead", Heart Rhythm Society 2007.03.041 (2007) ("Early Failure"), the Minneapolis Heart Institute's experience reflected that, between September 2004 and February 2007, 583 patients were implanted with Sprint Fidelis Model 6949 Leads, and nine patients received other Sprint Fidelis models. During that time, six patients experienced Sprint Fidelis Model 6949 Lead failures. The failed Sprint Fidelis Model 6949 Leads had been implanted by various electrophysiologists, cardiologists and thoracic surgeons. The average time to failure was fourteen months (based on a range of four to twenty-three months). *Early Failure*, p. 893.

27. The study compared the actuarial survival of the 583 Sprint Fidelis Model 6949 Leads implanted at the Minneapolis Heart Institute to the survival of 285 Sprint Quattro Model 6947 Leads implanted at the Institute between November 2001 and March 2007. The difference in survival between the Sprint Fidelis Model 6949 lead and the Sprint Quattro Secure Model 6947 lead was extremely significant. The failure rate for the Sprint Fidelis Model 6949 lead was 1-2% during the first two years of implant and was ten times greater than the failure rate for the Sprint Quattro Secure Model 6947 lead. *Early Failure*, p. 893-894.

28. The significant number of lead failures involved lead fractures of the PACE-sense conductor or coil in the Sprint Fidelis Model 6949. The fracture rate for the Sprint Fidelis Leads was three times higher than the fracture rate of the Quattro Model 6947. *Early Failure*, p. 894-895.

29. Another study, conducted at Cornell University Medical Center by Sunil Mirchandani, et al., found "(a) 17% incidence of abnormal right ventricular sensing during follow-up of patients implanted with the Medtronic Sprint Fidelis ICD Lead," necessitating "an early revision of the system in 4% of patients." *See* Abstract of *Defibrillator Leads: Is Smaller Necessarily Better?, 2006*, available at http://vivo.lihrary.comell.edu/entity?home=&id=30168.

30. Medtronic has not disclosed the precise mechanism of the Sprint Fidelis Lead fracture failures. However, it appears that the defect in the Sprint Fidelis may be attributable to the small diameter of the coil and conductors and the fact that, in light of this small diameter, it is subject to stress damage both during and after implant. Fracture eventually occurs when the conductor is critically overstressed. The number of fractures that have been observed in these Leads indicates that there is a clear defect in the Leads themselves, and that defect was demonstrated in the 6949 lead that was implanted in the Plaintiff.

31. A review of the FDA's MAUDE database, which contains reports of adverse events associated with the use of medical devices, discloses that, as of July 2007, over 1000 Medical Device Reports ("MDR"s) regarding Sprint Fidelis Leads had been filed since September 2004. The most frequent complaints were fracture and inappropriate shocks, and the most common observations were high impedance, oversensing and noise, and failure to capture or high threshold.

32. Medtronic analyzed approximately 125 of those Leads that were returned to Medtronic before July 2006. According to the relevant MDR reports, Medtronic concluded that 77 out of 125 Leads (or 62%) were defective. The predominant manifestation of the defect was conductor fracture, involving the PACE-sense conductor and coil or the high voltage (defibrillation) conductor. PACE-sense conductor or coil fracture was manifested by inappropriate shocks or oversensing/noise and high impedance, while high voltage conductor fracture was primarily linked to high impedance.

33. Medtronic filed more than 350 additional MDRs regarding the Sprint Fidelis Leads between August 2006 and February 2007. Medtronic did not include similar analysis of those Leads in the MDRs filed by Medtronic during this period.

34. On March 21, 2007, Medtronic issued a physician advisory, in the nature of a "Dear Doctor Letter," that advised physicians of "the higher than expected conductor fracture rates in Sprint Fidelis Leads." Medtronic claims in that letter to be investigating reports of lead failures; however, still represents that the Sprint Fidelis Leads are performing consistent with, and "in line with other Medtronic Leads, and consistent with lead performance publicly reported by other manufacturers." This letter also states, "...variables within the implant procedure may contribute significantly to these fractures... For conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral area." At no time prior to this letter did Medtronic warn physicians that its Leads must be specially handled during the implantation procedure or that they could "severely bend" or "kink" if they are implanted using certain accepted implant techniques.

35. On October 15, 2007, Medtronic issued a recall of all unimplanted Sprint Fidelis Leads, citing several deaths related to the Leads. Medtronic recommended that implanted Sprint Fidelis Leads be monitored.

36. Medtronic's representation of the consistency of the performance of the Sprint Fidelis Leads is untrue in light of the reported experience with the Leads and the various issues included in the MAUDE database reports.

37. At all times relevant, Medtronic misrepresented the safety of the Sprint Fidelis Leads and negligently manufactured, marketed, advertised, promoted, sold, and distributed the Leads as safe devices to be used together with ICDs for prophylactic treatment of patients with prior myocardial infarction and decreased ejection fraction, ventricular arrhythmias, and patients who are at high risk for developing such

arrhythmias. Some patients are dependent on such devices to maintain an appropriate heart rhythm, and therefore, adequate cardiac output. For these patients, failure of the Leads connected to the ICD can cause sudden faintness, or loss of consciousness, and can result in death.

38. At all times relevant, Medtronic failed to warn that the Sprint Fidelis leads were prone to breakage or that particular processes should be implemented in order to avoid breaking the Sprint Fidelis Leads.

39. As a result of their defective design and manufacture, Medtronic's Sprint Fidelis Leads suffer fracture, leading to malfunction in the transmission of the electric signal from the ICD to the patient's heart.

## ALLEGATIONS

40. At all times relevant, the Sprint Fidelis (collectively the "Leads") were researched, developed, manufactured, marketed, promoted, advertised and sold by Medtronic.

41. At all times relevant, Medtronic misrepresented the safety of the Sprint Fidelis Leads, and negligently manufactured, marketed, advertised, promoted, sold and distributed the Leads as safe and effective devices to be used for implantation with ICDs for prophylactic treatment of patients with prior myocardial infarction and a limited ejection fraction, patients who have had spontaneous and/or inducible life-threatening ventricular arrhythmias, and patients who are at high risk for developing such arrhythmias.

42. At all times relevant to this action, Medtronic knew, and had reason to know, that the Sprint Fidelis Leads were not safe for the patients for whom they were prescribed and implanted, because the Leads fractured and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in some patients, catastrophic injuries and deaths.

43. At all times relevant to this action, Medtronic knew, and had reason to know, that its representations that the Sprint Fidelis Leads were easier to implant and based on "proven" technology were materially false and misleading.

44. Approximately 129,000 of the affected devices remain in service in the United States and in other countries.

45. As a result of this defective design and manufacture, the Sprint Fidelis Leads can cause serious physical trauma and/or death. Medtronic knew and had reason to know of this tendency and the resulting risk of injuries and deaths, but concealed this information and did not warn Plaintiff or her physicians, preventing Plaintiff, her physicians, and the medical community, from making informed choices about the selection of Leads for implantation. Medtronic designed, manufactured, marketed, promoted, sold, and distributed 4 models of defective Leads, including the Sprint Fidelis 6949 LFJ extendable/retractable screw fixation (S) model; the 6948 LFH tuned fixation (T) model; the 6931 LFT S fixation; and the 6930 LFK fixation (T) model. All of the aforementioned models contain the same defect.

46. The Sprint Fidelis Leads were originally approved for sale by the FDA in September 2004.

47. The Sprint Fidelis Leads are uniformly defective in that they are prone to fracture of the pace-sense conductor and coil and the I-IV conductor, causing them to fail to function in a manner which may not he immediately detectable by the patient. The malfunctioning can lead to terrifying inappropriate defibrillation shocks, failure to deliver appropriate (life-giving) defibrillation therapy and death.

48. There is no test that predicts whether the Sprint Fidelis Leads will fail.

49. To this day, Medtronic has refused to suggest replacement of the defective Sprint Fidelis Leads in its patients, even though in patients whom these defects have been discovered, emergency replacement of the Leads is required.

50. Medtronic's failure to document or follow-up on the known defects in its Sprint Fidelis Leads, and concealment of known defects from the FDA, patients and the medical community constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

51. March 2007 was the earliest date anyone could have known about or discovered the existence of the defect in the Sprint Fidelis Leads, when the first physician advisory was sent by Medtronic to physicians concerning the fragile nature of these Leads.

52. Medtronic is estopped from relying on the Statute of Limitations defense because Medtronic actively concealed the lead defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians or patients. Instead of revealing the defects, Medtronic continued to represent its products as safe for their intended use.

53. Medtronic's conduct, as described in the preceding paragraphs, amounts to conduct intentionally committed, which Medtronic must have realized was dangerous, wanton and reckless, without regard to the consequences, rights and safety of patients.

54. Medtronic's failure to provide adequate and accurate information has resulted in thousands of patients' relying upon the proper functioning of these Sprint Fidelis Leads, and they, along with their physicians, have been vigorously attempting to assess the risks that they now face.

55. Patients and physicians remain uninformed and confused about whether the devices should be explanted, or even whether all of the defects have been disclosed.

56. Due to incomplete, inconsistent, and/or confusing information published by Medtronic, it remains unclear as to how many patients are affected by these defective Leads, although based on the population of Medtronic patients whose claims are asserted in this complaint, it is likely to be at least 1,500 and could be as high as 6,000 heart patients in the United States.

57. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to Plaintiff.

58. There exists and, at all times herein mentioned, existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

59. At all times herein mentioned, Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff's damages.

60. At all times herein mentioned, the officers and/or directors of the Defendants named herein, participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff.

**PLAINTIFF**

61. Plaintiff, Barbara Berry, was born on October 14, 1940 and has a cardiovascular condition that necessitates the use of an implantable cardiac pacemaker/defibrillator. Berry was implanted with a cardiac pacemaker/defibrillator combination (an "ICD"), more specifically, a Medtronic Maximo VR, Model Number 7232CX, Serial Number PRN117355H, on January 12, 2006 at the St. Joseph Hospital. The ICD was attached to her heart with a lead wire system called a Sprint Fidelis Lead, Model Number 6949, Serial Number LFJ092091V, also manufactured by Medtronic.

62. The Sprint Fidelis Lead implanted in Berry's heart was designed, manufactured, sold and distributed by Defendants, and was intended to be used by surgeons for heart defibrillator implantation surgeries. Defendants represented that Sprint Fidelis Leads were appropriate and suitable products for such purposes.

63. The Sprint Fidelis Lead in Berry's body presents a serious ongoing health risk due to its defective design and/or manufacture.

64. As a direct and proximate result of Defendants' defective design, manufacture, function and/or inadequate warnings regarding the Sprint Fidelis Lead, Berry's lead is defective. Berry has, and will continue to sustain, injuries and damages, including but not limited to, severe emotional distress, medical monitoring, as well as the constant threat of extreme risk of grave injury or possible death.

65. As a direct and proximate result of the acts and omissions of Defendants, Berry has suffered emotional and psychological distress and anxiety which includes the fear of sudden death related to the defective nature of his device.

66. Due to the intentional, reckless, grossly negligent, willful and wanton, acts and omissions of the Defendants, Plaintiff prays for punitive damages in an amount commensurate with Defendants' culpability therefore.

## CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF
### (Strict Products Liability/Defective Product)

67. Plaintiff re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

68. At all relevant times hereto, Medtronic was engaged in the business of designing, manufacturing, assembling, promoting, advertising, selling, and distributing the Sprint Fidelis Leads for ultimate sale to, and implantation in, heart disease/disorder patients. Medtronic designed, manufactured,

assembled, and sold the Sprint Fidelis Leads to hospitals and physicians, knowing that they would be thereby sold to patients with heart diseases and disorders, including the Plaintiff.

69. Medtronic's Sprint Fidelis Leads were expected to and did reach the Plaintiff without substantial change in their condition as manufactured and sold by Medtronic. In light of the defects described herein, at the time the Leads reached the Plaintiff, they were in a condition not contemplated by any reasonable person among the expected users of the devices, and were unreasonably dangerous to the expected users of the devices when used in reasonably expectable ways of handling or consumption.

70. The Sprint Fidelis Leads designed, manufactured, assembled, and sold by Medtronic to Plaintiff was in a defective condition unreasonably dangerous to any user or consumer of the devices, and Plaintiff was, and is, a person that Medtronic should reasonably have foreseen as being subject to the harm caused by the devices' defective condition. Moreover, Medtronic failed to warn Plaintiff and/or Plaintiff's treating physicians about the known or knowable risks and defects associated with the Sprint Fidelis Leads.

71. Plaintiff used the Leads in the manner in which the Leads were intended to be used. This has resulted in severe and life threatening injuries to Plaintiff.

72. Plaintiff was not aware of, and could not in the exercise of reasonable care have discovered, the defective nature of Medtronic's Sprint Fidelis Leads, nor could he have known that Medtronic designed, manufactured or assembled the Leads in a manner that would increase the risk of bodily injury to him.

73. As a direct and proximate result of Medtronic's design, manufacture, assembly, marketing and sales of the Sprint Fidelis Leads, Plaintiff has sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and consequential damages, and is therefore entitled to compensatory relief according to proof, and entitled to a declaratory judgment that Medtronic is liable to them for breach of its duty to Plaintiff and Medtronic's failure to provide a safe and effective medical device; and Plaintiff is entitled to equitable relief as described below. As to a more complete recitation of Plaintiff's injuries, Plaintiff craves reference to Paragraphs 61-66 hereinabove.

74. Medtronic's Sprint Fidelis Leads constitute a product dangerous for its reasonably intended use, due to defective design, manufacture, assembly, and marketing. Medtronic is therefore liable to Plaintiff in an amount according to proof.

**SECOND CLAIM FOR RELIEF**
**(Negligence)**

75. Plaintiff re-alleges the allegations contained in the foregoing paragraphs, as if set forth verbatim.

76. Medtronic had a duty to Plaintiff to provide a safe product in design and manufacture, to notify the FDA of design flaws, and to warn the FDA and Plaintiff of the defective nature of the Sprint Fidelis Leads. Medtronic breached its duty of reasonable care to Plaintiff by incorporating a defect into the design of the Sprint Fidelis Leads, thereby causing Plaintiff's injuries.

77. Medtronic breached its duty of reasonable care to Plaintiff by manufacturing and assembling the Sprint Fidelis Leads in such a manner that they were prone to fracture and fail to operate and malfunction and expose Plaintiff to life threatening physical trauma.

78. Medtronic breached its duty of reasonable care to Plaintiff by failing to notify the FDA at the earliest possible date of known design defects in the Leads. Further, Medtronic breached its duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

79. As a direct and proximate result of the carelessness and negligence of Medtronic as set forth in the preceding paragraphs, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages, are entitled to compensatory damages and equitable and declaratory relief according to proof. Medtronic's egregious misconduct alleged above also warrants the imposition of punitive damages against Medtronic. As to a more complete recitation of Plaintiff's injuries, Plaintiff craves reference to Paragraphs 61-66 hereinabove.

**THIRD CLAIM FOR RELIEF**
**(Breach of Express Warranties)**

80. Plaintiff re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

81. Defendants expressly warranted to Plaintiff by and through Defendants and/or their authorized agents or sales representatives, in publications, the internet, and other communications intended for medical patients, and the general public, that the defective Leads were safe, effective, fit and proper for their intended use.

82. In allowing the implantation of the defective Leads, Plaintiff relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the defective Leads were not safe and were unfit for the uses for which they were intended.

83. Through its sale of the defective Leads, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

84. Any disclaimers of express warranties are ineffectual as they were not provided to Plaintiff or otherwise made known to Plaintiff. In addition, any such disclaimers are unconscionable.

85. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff has sustained economic losses and other damages for which he is entitled to compensatory damages in an amount to be proven at trial. Any disclaimer of consequential damages is invalid as the limited remedy provided fails in its essential purpose to redress the harm and damages to Plaintiff in that it, in effect, provides no remedy at all for the defect necessary to be redressed. In addition, any such disclaimer of consequential damages in unconscionable. Defendants are therefore liable to Plaintiff in an amount according to proof. As to a more complete recitation of Plaintiff's injuries, Plaintiff craves reference to Paragraphs 61-66 hereinabove.

**FOURTH CLAIM FOR RELIEF**
**(Breach of Implied Warranty)**

86. Plaintiff re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

87. Medtronic impliedly warranted that its Sprint Fidelis Leads, which Medtronic designed, manufactured, assembled, promoted and sold to Plaintiff, was merchantable and fit and safe for ordinary use. Medtronic further impliedly warranted that its Sprint Fidelis Leads were fit for the particular purpose of providing prophylactic treatment of patients with a variety of medical issues, including prior myocardial infarction and a limited ejection fraction, spontaneous and/or inducible life-threatening ventricular arrhythmias, and a high risk for developing such arrhythmias.

88. Medtronic further impliedly warranted that its Sprint Fidelis Leads were based on "proven" lead technology and that the Sprint Fidelis Leads were easier to implant.

89. Medtronic's Sprint Fidelis Leads were defective, unmerchantable, and unfit for ordinary use when sold, and unit for the particular purpose for which they were sold, and subjected Plaintiff to severe and permanent injuries and death. Therefore, Medtronic breached the implied warranties of merchantability and fitness for a particular purpose when its Lead was sold to Plaintiff, in that the Lead was defective and has fractured and otherwise failed to function as represented and intended.

90. As a direct and proximate result of Medtronic's breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, and economic losses, and are therefore entitled to compensatory damages and equitable relief according to proof. As to a more complete recitation of Plaintiff's injuries, Plaintiff craves reference to Paragraphs 61-66 hereinabove.

**FIFTH CLAIM FOR RELIEF**
**(Intentional Infliction of Emotional Distress)**

91. Plaintiff re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

92. Medtronic engaged in extreme and outrageous conduct, knowingly and/or recklessly marketing defective Leads, knowingly and/or recklessly concealing a known and potentially fatal defect from Plaintiff, and knowingly and/or recklessly misrepresenting the quality and usefulness of the Sprint Fidelis Leads.

93. As a direct result of Medtronic's misconduct, Plaintiff has sustained and will continue to sustain physical injuries and/or death, economic losses, and other damages.

94. Medtronic intended to cause Plaintiff severe emotional distress, or acted with reckless disregard for the Plaintiff's emotional state.

95. Plaintiff did, in fact, incur (and will continue to incur) severe emotional distress as a result of Medtronic's misconduct. Accordingly, Plaintiff is entitled to compensatory damages and equitable and declaratory relief according to proof. As to a more complete recitation of Plaintiff's injuries, Plaintiff craves reference to Paragraphs 61-66 hereinabove.

96. Medtronic's misconduct alleged above warrants the imposition of punitive damages against Medtronic.

**SIXTH CLAIM FOR RELIEF**
**(Negligent Infliction of Emotional Distress)**

97. Plaintiff re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

98. Medtronic carelessly and negligently manufactured, marketed and sold defective Sprint Fidelis Leads to Plaintiff, carelessly and negligently concealed these defects from Plaintiff, and carelessly and negligently misrepresented the quality, safety and usefulness of the Leads.

99. Plaintiff was directly involved in and directly impacted by Medtronic's carelessness and negligence, in that he has sustained and will continue to sustain severe physical injuries and/or death, economic losses, and other damages as a direct result of the decision to purchase, use and have implanted in his body a defective and dangerous product manufactured, sold and distributed by Medtronic.

100. Medtronic's misconduct as alleged above has caused Plaintiff to suffer severe emotional trauma, physical consequences and long continued emotional disturbance. Plaintiff is therefore entitled to compensatory damages and equitable and declaratory relief according to proof. As to a more complete recitation of Plaintiff's injuries, Plaintiff craves reference to Paragraphs 61-66 hereinabove.

**SEVENTH CLAIM FOR RELIEF**
**(Unjust Enrichment)**

101. Plaintiff re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

102. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase of Defendants' defective Leads by Plaintiff.

103. Defendants have voluntarily accepted and retained these profits and benefits, derived from the Plaintiff, with full knowledge and awareness that, as a result of Defendants' wrongdoing, Plaintiff was not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiff, as a reasonable consumer, expected.

104. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of the Plaintiff, who is entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

**EIGHTH CAUSE OF ACTION**
**(Negligent Misrepresentation)**

105. Plaintiff re-alleges the allegations contained in the foregoing paragraphs as if set forth verbatim.

106. At the time Defendants manufactured, designed, marketed, sold and distributed the defective Leads for use by the Plaintiff, Defendants knew of should have known of the use for which the defective Leads were intended and the serious risks and dangers associated with such use of these defective Leads.

107. Defendants owed a duty to treating physicians and ultimate end users of the defective Leads, including Plaintiff, to accurately and truthfully represent the risks of the Leads. Defendants breached that duty by misrepresenting and/or failing to adequately warn of the risks of the Leads, effects of which Defendants knew or in the exercise of diligence should have known, to the treating physicians and ultimate end users, including Plaintiff.

108. As a direct and proximate result of the Defendants' wrongful conduct, Plaintiff has sustained, and will continue to sustain, severe and physical injuries and/or death, severe emotional distress, economic losses and other damages for which he is entitled to statutory, compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiff for all general, special and equitable relief to which Plaintiff is entitled by law. For a more complete recitation of the injuries suffered by Plaintiff, Plaintiff craves reference to Paragraph 61-66 hereinabove.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for judgment against Medtronic as follows:

a. For the equitable relief requested;

b. For compensatory damages according to proof;

c. For punitive or exemplary damages against Medtronic, consistent with the degree of Medtronic's reprehensibility and the resulting harm or potential harm to Plaintiff, and in an amount sufficient to punish Defendants and deter others from similar wrongdoing;

d. For declaratory judgment that Defendants are liable to Plaintiff for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Medtronic's wrongdoing;

e. For a restitution and disgorgement of profits;

f. For an award of attorneys' fees and costs;

g. For prejudgment interest and the costs of suit; and

h. For such other and further relief as this Court may deem just and proper.

**JURY DEMAND**

Plaintiff hereby demands a trial by jury in this case as to such issues so triable.

Dated: May 13, 2008

THE BRANDI LAW FIRM

By: _____

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